DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-943/S-015
NDA 20-011/S-022
NDA 20-708/S-013

TAP Pharmaceutical Products, Inc.
Attention: Jessie Y. Lee, Ph.D., RAC
Senior Regulatory Product Manager
675 North Field Drive
Lake Forest, IL 60045

14 NOV 2001

Dear Dr. Lee:

Please refer to your supplemental new drug applications dated October 16, 2001, received October 17, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA Number	Supplement Number	Drug Name
19-943	S-015	Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension)
20-011	S-022	Lupron Depot® 3.75 mg (leuprolide acetate for depot suspension)
20-708	S-013	Lupron Depot®-3 Month 11.25 mg (leuprolide acetate for depot suspension)

These "Changes Being Effected" supplemental new drug applications provide for the following addition to the **PRECAUTIONS** section of the package insert to provide information for patients regarding depression and memory disorder.

PRECAUTIONS
Information for Patients

"5. Patients should be counseled on the possibility of the development or worsening of depression and the occurrence of memory disorders."

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 16, 2001).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999).

Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-943/S-015, 20-011/S-022, 20-708/S-013." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Senior Regulatory Associate, at (301) 827-4260.

Sincerely,

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research